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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,625	02/01/2001	Jana Sawynok	DALHO1290-1	7582

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STEPHEN E. REITER
FOLEY & LARDNER
P. O. BOX 80278
SAN DIEGO, CA 92138

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,625

Applicant(s)

SAWYNOK ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44,49-53,74-78,80,82 and 83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44,49-53,74-78,80,82 and 83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt of amendment and remarks dated 10-13-04 is acknowledged.

Claims 1-43, 45-48, 54-73, 79 and 81 are canceled. Claims 44, 49-53, 74-78, 80, 82 and 83 are pending.

Response to Amendment

Upon careful consideration of the amended claims and applicants' response, the finality of the rejection of the last Office action is withdrawn and the following rejection is applied:

Claim Rejections - 35 USC § 102

Claims 44, 49-51, 80 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,266,571 to Amer et al (Amer).

Amer discloses topical composition for treating hemorrhoids comprising nefazodone. The composition is administered in the form of a gel, cream or lotion, which read on the claimed penetration enhancer. Further, Amer discloses pH-adjusting agents that meet the claimed neutralizing agents and other carriers for the formulation (abstract, col. 2, lines 52-54, col. 3, lines 45-64, col. 5, lines 10 through col. 6, line 18 and claims).

Claims 74 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 9637198 to Eisenburger et al (hereafter WO)

WO discloses an inhalation composition comprising tri- and/or tetra-cyclic antidepressants, in particular the claimed compound maprotiline, for the treatment of asthma. The composition is in the form of an aerosol (abstract). Thus, WO anticipates instant claim.

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Claims 44, 49-53, 74-78, 80, 82 and 83 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,290,986 to Murdock et al (Murdock).

Murdock discloses transdermal compositions comprising antidepressants such as bupropion, robexetine etc., and particularly, tricyclic-antidepressants such as amytryptiline and nefazodone etc. (abstract, col. 1, lines 10-25, examples 5, 7, 19, 27, 31 and 35). Murdock discloses the carriers, and polymers such as pluronic, as injections (col. 2, lines 45-59, example 38). Thus, Murdock anticipates instant claims.

Claim Rejections - 35 USC § 103

Claims 52, 53, 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amer in view of US 6,290,986 to Murdock et al (Murdock).

Amer fails to teach the claimed encapsulation of the antidepressant in a slow release delivery vehicle and also lacks the teachings of liposome or a polymer stabilized crystal.

Murdock teaches a method and composition for transdermal administration of pharmacological agents, wherein the pharmaceuticals are delivered using a matrix of lecithin organogel that acts as a penetration enhancer. Murdock teaches psychopharmaceuticals, in particular antidepressants such as, bupropion and robexetine, more particularly tricyclic antidepressants, nefazodone. It would have been obvious for one of ordinary skill in the art at the time of the instant invention to prepare the antidepressant compounds of Amer in the form of gel matrix containing penetration enhancer or absorption agents such as lecithin gel of Murdock because Murdock suggests that the lecithin organogel carrier helps delivers

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psychopharmaceuticals via transdermal system or injection system, as opposed to oral and thus avoid the undesirable side effects due to the oral administration i.e., sedation, liver damage, weight gain etc.

Response to Arguments

Applicant's arguments filed 10-13-2004 have been fully considered but they are not persuasive.

In response to Applicants' amendment, the previous new matter rejection has been withdrawn. Applicants argue that the provisional rejection of claims 37-43, 73, 79 and 81, as being anticipated by Amer is moot in view of the cancellation of the claims. However, the present rejection is applied a different set of claims and accordingly, applicants argument is moot. Further, applicants argument with respect to provisional rejection of claims 75, 77, 78, 80, 82 and 83 as being obvious over Amer in view of Knepp have been consideration but are moot in view of the withdrawal of the previous rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
December 15, 2004



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600